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DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			EXAMINER TANNER, JOCELIN C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,672	Applicant(s) KUEHNER ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed 28 July 2009. Claims 1-24 are currently pending. The Examiner acknowledges the amendments to the specification, claims 1-12 and new claims 13-24.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-4, 6-9, 12, 16-18, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Reilly et al. (US Patent No. 5,916,197).**

3. Regarding claim 1, Reilly et al. disclose an arrangement of a plurality of supply cylinders (20), each supply cylinder including a piston (70) therein and are capable of storing a working fluid that can be expelled by pistons through outlets (30), wherein the working fluid is enclosed within each supply cylinder in a leak proof manner wherein a sealing member (72) creates a sealing engagement until it is expelled by the pistons through the outlet, a pressure conduit (60) in communication with the outlets and each of the supply cylinders and into which a working fluid is expelled, at least one actuation device (120) to actuate the pistons, and a change-over device (110) that rotates to drive pistons in a timed sequence to eliminate pulsatile flow and consecutively empty

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supply cylinders (column 3, lines 1-10, 30-33, 55-65, column 5, lines 1-10, 26-35, 56-65).

4. Regarding claim **2**, Reilly et al. disclose a change-over device (11) that is capable of providing consecutive actuation periods of each of the pistons (70) such that expulsion of the fluid into the pressure conduit is uninterrupted (column 5, lines 56-60).

5. Regarding claim **3**, Reilly et al. disclose sealing devices (40) are provided to provide leak proof connection to each fluid outlet wherein the valves ensure the desired direction of flow is maintained (column 5, lines 5-9).

6. Regarding claim **4**, Reilly et al. disclose a plurality of actuation devices (120) (column 5, lines 56-67).

7. Regarding claim **6**, Reilly et al. disclose a transport gasket (72) that is provided at the outlet of each supply cylinder (column 5, lines 41-45).

8. Regarding claims **7, 8 and 12**, Reilly et al. disclose a change-over magazine (10) that defines chambers that closely surround and receive a group of supply cylinders and piston arrangements and can be connected to the pressure conduit to form a single unit and that is capable of forming a single-use unit (column 4, lines 11-14, column 5, lines 18-25, Fig. 1).

9. Regarding claim **9**, Reilly et al. disclose collection devices located between the check valves (40) and the outlet ports (30) wherein working fluid from the supply cylinders (20) are guided to the pressure conduit (60) (Fig. 1B).

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10. Regarding claim **16**, Reilly et al. disclose a plurality of supply cylinders that are capable of being individually replaced (Fig.1).

11. Regarding claim **17**, Reilly et al. disclose a change-over magazine (10) having integrally formed supply cylinders (20) therein (Fig. 2B).

12. Regarding claims **18 and 22**, Reilly et al. disclose a device outlet (60), a plurality of supply chambers (20) enclosing a working fluid, each chamber defined by a piston (70), at least one chamber outlet (30) and at least one supply chamber wall, a conduit that provides fluid communication between the device outlet (60) and the at least one chamber outlet (30) of each of the plurality of supply chambers, each of the plurality of supply chambers includes a seal (40) that hermetically encloses the working fluid in the supply chamber until a high pressure is applied to the working fluid via the piston (70) (column 5, lines 1-17).

13. Regarding claim **23**, Reilly et al. disclose an opening within a magazine (10) that is capable of interchangeably receiving a supply device having a plurality of supply chambers (20) and a plurality of actuation devices (120), each of the plurality of actuation devices actuating the piston of a respective one of the plurality of supply chambers in a single direction (column 3, lines 1-10, 30-33, 55-65, column 5, lines 1-10, 26-35, 57-67, Fig. 1).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of Palmer (US Patent No. 4,820,272).

16. Regarding claims **5 and 19**, Reilly et al. discloses all of the limitations previously discussed except for a back-flow barrier that prevents the piston from being pushed back into a previous position.

Palmer teaches a device including a piston (24) disposed within a cylinder (11) wherein the piston includes sealing rings (25) that engage the inner wall of the cylinder at the engagement zones (17, 18) to block the removal of the piston (column 2, lines 39-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a back-flow barrier to the pistons of Reilly et al., as taught by Palmer, to prevent the re-use of the piston.

17. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of McGregor (US Patent NO. 5,116,313).

18. Regarding claims **10 and 11**, Reilly et al. discloses ventilation devices (630) within the change-over magazine (10) wherein air is removed, however, Reilly et al. fails to disclose the ventilation devices being provided between the outlets of the supply cylinders and the pressure conduit.

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McGregor teaches a device including a cylinder (10') with a piston (15) disposed within wherein air is released through vent (49) between the outlets of the supply cylinders and the pressure conduit (13) (column 5, lines 65-68, column 6, lines 1-3, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Reilly et al. with ventilation devices between the pressure conduit and supply cylinders, as taught by McGregor, since it would not affect the functioning of the device and for the predictable result of removing air bubbles prior to the injection of the medium into the patient.

19. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of Schwartz et al. (US PGPub No. 2003/0009132A1).

20. Regarding claims **13 and 15**, Reilly et al. disclose all of the limitations previously discussed except for a supply cylinders that are arranged in the change-over magazine around a central axis of the change-over magazine.

Schwartz et al. teach a device capable of releasing liquid within tissue including a rotatable magazine (130) having multiple cylinders (46) each containing pistons, the magazine being moved by an indexing motor (136) [0085].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Reilly et al. with a rotatable magazine having supply cylinders arranged radially therein, as taught by

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Schwartz et al., to increase the operating range of the device and allow the user to determine the appropriate cylinder for the desired fluid ejection.

21. Regarding claim **14**, Reilly et al. disclose a plurality of supply cylinders that are arranged parallel to the central axis of the change-over magazine (Fig.1).

22. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of Moutafis et al. (US Patent 6,216,573).**

23. Regarding claim **20**, Reilly et al. disclose a device outlet (60), a plurality of supply chambers (20) enclosing a working fluid, each chamber defined by a piston (70), at least one chamber outlet (30) and at least one supply chamber wall, a conduit that provides fluid communication between the device outlet (60) and the at least one chamber outlet (30) of each of the plurality of supply chambers, each of the plurality of supply chambers includes a seal (40) that hermetically encloses the working fluid in the supply chamber until a high pressure is applied to the working fluid via the piston (70) (column 5, lines 1-17). However, Reilly et al. fail to disclose the working fluid as being sterile.

Moutafis et al. teach a device having pumping system that supplies sterile saline to a conduit (36) (column 5, lines 47-51).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Reilly et al. with a fluid sterile, as taught by Moutafis et al., since it is well known to use a sterile fluid when performing a surgical procedure.

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24. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of Moutafis et al. (US Patent 6,216,573), as applied to claim 20 above, and further in view of Palmer (US Patent No. 4,820,272).

25. Regarding claim **21**, the combination of Reilly et al. and Moutafis et al. discloses all of the limitations previously discussed except for a back-flow barrier that prevents the piston from being pushed back into a previous position.

Palmer teaches a device including a piston (24) disposed within a cylinder (11) wherein the piston includes sealing rings (25) that engage the inner wall of the cylinder at the engagement zones (17, 18) to block the removal of the piston (column 2, lines 39-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a back-flow barrier to the pistons of the combination of Reilly et al. and Moutafis et al., as taught by Palmer, to prevent the re-use of the piston.

26. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US Patent No. 5,916,197) in view of Libermann (US PGPub No. 2003/0176833A1).

27. Regarding claim **24**, Reilly et al. disclose a mechanism for sensing pressure in connection with the outlet of the pump system to measure the pressure. However, Reilly et al. fail to disclose a control device and a plurality of sensors associated with

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the plurality of actuation devices such that a signal is provided to the control device that indicates when the actuation device has reached a final position.

Libermann teaches sensors (26, 28) that are coupled to a controller (30) and a container (12, 14) and wherein the state of the container is received by the controller via the signals of the sensors with respect to the quantity of the fluid in each container [0035-0037].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Reilly et al. with sensors, as taught by Libermann, to provide the user with signals to control the quantity of liquid therein [0034].

Response to Arguments

28. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The Applicant contends that Reilly et al. fails to disclose supply chambers having a working fluid enclosed therein. However, Reilly et al. disclose supply chambers that draw a liquid medium into the chamber and hold the liquid therein until the liquid is pressurized and released into an outlet channel (column 5, lines 26-32), therefore, a working medium is enclosed within the chamber for a period of time. The Applicant contends that there is no motivation to combine Reilly et al. with Palmer since the pressurizing device of Reilly et al. depends on the pistons operating in a reciprocating manner. However, Reilly et al. discloses that it may be desirable to include a mechanism for stopping flow of the injection medium,

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therefore, it would have been obvious to have provided a means to prevent the movement of the pistons to stop the fluid injection.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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